

Drug Enforcement Administration, Justice

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inventory to 50 percent of the estimated net disposal for that year.

§ 1315.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a chemical may file with the Administrator an application on DEA Form 189 for an increase in the registrant's quota to meet the registrant's estimated net disposal, inventory, and other requirements during the remainder of that calendar year.

(b) The Administrator, in passing upon a registrant's application for an increase in the individual manufacturing quota, shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the calendar year. In passing upon the application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the chemical to be manufactured under § 1315.11 exceeds the aggregate of all the individual manufacturing quotas for the chemical, and the equitable distribution of such excess among other registrants.

§ 1315.26 Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a chemical that he has previously fixed to prevent the aggregate of the individual manufacturing quotas and import quotas outstanding or to be granted from exceeding the assessment of annual needs that has been established for that chemical pursuant to § 1315.11, as adjusted pursuant to § 1315.13. If a quota assigned to a new manufacturer pursuant to § 1315.23(b), or if a quota assigned to any manufacturer is increased pursuant to § 1315.24(c), or if an import quota issued to an importer pursuant to § 1315.34, causes the total quantity of a chemical to be manufactured and imported during the year to exceed the assessment of annual needs that has been established for that chemical pursuant to § 1315.11, as adjusted pursuant to § 1315.13, the Administrator may pro-

portionately reduce the individual manufacturing quotas and import quotas of all other registrants to keep the assessment of annual needs within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to § 1315.24(b) or §§ 1301.36, 1309.43, 1309.44, or 1309.45 of this chapter or is abandoned pursuant to § 1315.27.

§ 1315.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to § 1315.23 may at any time abandon his right to manufacture all or any part of the quota by filing with the Drug & Chemical Evaluation Section a written notice of the abandonment, stating the name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical and the amount which he has chosen not to manufacture. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

Subpart D—Procurement and Import Quotas

§ 1315.30 Procurement and import quotas.

(a) To determine the estimated needs for, and to insure an adequate and uninterrupted supply of, ephedrine, pseudoephedrine, and phenylpropanolamine the Administrator shall issue procurement and import quotas.

(b) A procurement quota authorizes a registered manufacturer to procure and use quantities of each chemical for the following purposes:

(1) Manufacturing the bulk chemical into dosage forms.

(2) Manufacturing the bulk chemical into other substances.

(3) Repackaging or relabeling the chemical or dosage forms.

(c) An import quota authorizes a registered importer to import quantities of the chemical for the following purposes:

(1) Distribution of the chemical to a registered manufacturer that has a procurement quota for the chemical.

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(2) Other distribution of the chemical consistent with the legitimate medical and scientific needs of the United States.

§ 1315.32 Obtaining a procurement quota.

(a) Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24 of this chapter, and who desires to use during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing (including repackaging or re-labeling), must apply on DEA Form 250 for a procurement quota for the chemical. A separate application must be made for each chemical desired to be procured or used.

(b) The applicant must state separately all of the following:

(1) Each purpose for which the chemical is desired.

(2) The quantity desired for each purpose during the next calendar year.

(3) The quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years.

(c) If the purpose is to manufacture the chemical into dosage form, the applicant must state the official name, common or usual name, chemical name, or brand name of that form. If the dosage form produced is a controlled substance listed in any schedule, the applicant must also state the schedule number and National Drug Code Number, of the substance.

(d) If the purpose is to manufacture another chemical, the applicant must state the official name, common or usual name, chemical name, or brand name of the substance and the DEA Chemical Code Number, as set forth in part 1310 of this chapter.

(e) DEA Form 250 must be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from the Office of Diversion Control Web site, and must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in

§ 1321.01 of this chapter for the current mailing address.

(f) The Administrator shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use:

(1) All quantities of the chemical necessary to manufacture products that the applicant is authorized to manufacture pursuant to § 1315.23; and

(2) Such other quantities of the chemical as the applicant has applied to procure and use and are consistent with his past use, his estimated needs, and the total quantity of the chemical that will be produced.

(g) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator shall increase or decrease the procurement quota of the person if and to the extent that he finds, after considering the factors enumerated in paragraph (f) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(h) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of ephedrine, pseudoephedrine, or phenylpropanolamine during the current calendar year, must, at or before the time of placing an order with another manufacturer or importer requiring the distribution of a quantity of the chemical, certify in writing to the other registrant that the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine ordered does not exceed the person's unused and available procurement quota of the chemical for the current calendar year. The written certification must be executed by a person authorized to sign the registration application pursuant to § 1301.13 or